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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,741	01/27/2004	Gene Michael Bright	PC11696A	2831
23913	7590	03/10/2006	EXAMINER	
PFIZER INC 150 EAST 42ND STREET 5TH FLOOR - STOP 49 NEW YORK, NY 10017-5612			BERNHARDT, EMILY B	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 03/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/766,741

Applicant(s)

BRIGHT ET AL.

Examiner

Emily Bernhardt

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 23-29 and 36-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-15, 17-19, 22 and 30-35 is/are rejected.
- 7) ☒ Claim(s) 9, 16, 20 and 21 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 6/3/04&9/16/04.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_.

Restriction to one of the following inventions is required under 35 U.S.C.

121:

- I. Claims 1-22,30-35, drawn to compounds, simple compositions and starting materials where Z=piperazines, classified in class 544, subclasses such as 362,370,372,etc; class 514 subclasses such as 253.04,254.05,etc.
- II. Claims 1-3,5-16,21,22,30-32,34 and 35, drawn to compounds, simple compositions and starting materials where Z=piperidines (both choices), classified in class 546, subclasses such as 208,211; class 514 subclass 326,etc.
- III. Claims 1,5-10,13-16,22,30,34 and 35, drawn to compounds, simple compositions and starting materials where Z=pyrrolidines (both choices), classified in classes 544,546 or 548, subclasses various as determined by actual species described; class 514, various subclasses.
- IV. Claims 23,26-29, drawn to multiple uses employing compounds of I, classified in class 514, subclasses 253.04,etc.
- V. Claims 23,26-29, drawn to multiple uses employing compounds of II, classified in class 514, subclass 326,etc.

- VI. Claims 23,26-29, drawn to multiple uses employing compounds of III, classified in class 514, subclasses various.
- VII. Claim 24-25, drawn to complex compositions and multi-uses employing compounds of I-III and additional active ingredients, classified in class 514, subclasses as may be determined by the exact nature of active ingredients employed.
- VIII. Claims 36-40, drawn to meta-substituted phenyl derivatives, classified in classes such as 544 or 546 or 548, subclasses various as determined by particular species.

If one of Groups IV-VI is elected, applicants must pick a single use. If Group VII is elected applicants must also choose a compound group, a specific use as well as a pair of species as the active ingredients.

The inventions are distinct, each from the other because of the following reasons: Compounds of groups I-III relate to compounds of considerable structural dissimilarity in view of the varying choices at A,B,D,E as well as at Y which permit a wide of variety hetero rings. Thus they are separately classified based at the very least on species recited in claim 21 . Each can support a patent as the compounds

of each group are capable of being utilized alone not in combination with other members listed in the Markush group.

Compounds within VII are not related to products in I-III as the structural feature always present in final products, namely para attachment of CH<sub>2</sub>-Y group is not present in VII and they are otherwise separately classified as they lack the "Z" ring .

Inventions I-III and IV-VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compounds have more than one use as evidenced by the method claims covering whole ranges of disorders . Additionally, the methods of use urged would raise different issues of patentability- at the very least 112 issues regarding the sole reliance on receptor binding to 5HT-7 receptor as a reasonable predictor of *in vivo* treatment for uses as varied as premature ejaculation, eating disorders , bipolar disorder, sleep disorders, etc.

Additionally, compounds of I-III embraced in VII may be old or obvious when separately employed but may be patentable due to superior, or synergistic properties not present for the individual components of I-III. Within group VII there is more than one invention as the claims embrace multiple combinations which require independent searches and which are not art-recognized equivalents in the art.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

During a telephone conversation with Mr. Joran on 2/9/06 a provisional election was made with right of traverse to prosecute the invention of I, claims 1-

22,30-35. Affirmation of this election must be made by applicant in replying to this Office action. Claims 23-29 and 36-40 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claims 1-8,10-15,17-19,22 and 30-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. The “Y” definition is not clear. It is first stated that up to 13 carbon atoms are permitted in the heteroaryl rings of Y but a few words later up to 20 are permitted. Thus intended scope is not clear.

2.Claim 30 is an independent claim and thus all variables need to be recited within the claim's scope. Note that "Z" is never defined or the R variables thereon. Thus dependent claims lack antecedent basis.

Claims 1-8,10-15,17-19 and 22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the "Y" rings recited in claims 9 and 16 and 20, does not reasonably provide enablement for remaining scope which includes up to 20 carbon atoms and an additional hetero atom in any array including fused ring systems as varied as furanopyridines, naphthyridines, diazines, thienopyrroles,etc. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Note In re Surrey 151 USPQ 724 regarding sufficiency of disclosure for a Markush group. Also see MPEP 2164.03 for enablement requirements in cases directed to structure-sensitive arts such as the pharmaceutical art.

Also note the criteria for enablement as set out in In re Wands cited in MPEP 2164.01(a),August 2000 edition, which includes factors such as:

1) Breadth of the claims- the claims cover compounds easily in the millions as pointed out above;



2) Level of unpredictability in the art- the invention is pharmaceutical in nature as it involves binding to serotonin (5HT-7) receptors. It is well established that “the scope of enablement varies inversely with the degree of unpredictability of the factors involved” and physiological activity is generally considered to be unpredictable. See *In re Fisher* 166 USPQ 18. A range of  $K_i$  values is reported for “preferred compounds” which is enormous- covering a 500 fold spread;

3) Direction or guidance- as stated above the compounds made are not representative of the instant scope as onlyazole rings have been made and presumably tested;

4) State of the prior art- The compounds are piperazine derivatives attached to an aromatic ring which in turn is ortho-substituted with phenyl which in turn is para-substituted with  $\text{CH}_2\text{Y}$  groups of varying structure. No such compounds are known in the art much less for the same activity relied on herein and thus do not evidence the many structural permutations permitted in the instant scope are known for at least one disclosed use in the prior art;

5) Working examples- Only a range has been reported for preferred compounds and thus no clear evaluation how the “Y” rings out of the many claimed might affect potency to a large or small degree.

In view of the above considerations, this rejection is being applied.

Claims 9,16 and 20-21 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims cover triazolyl as a choice for "Y" yet claim 1 permits only 2 hetero atoms can be present. See also triazolyl species in claim 21.

Claims 9,16,20 and 21 are objected to as being dependent upon a rejected base claim, but would be allowable **if nonelected subject matter is deleted** and if rewritten in independent form .

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is 571-272-0664.

If attempts to reach the examiner by telephone are unsuccessful, the acting supervisor for AU 1624, James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

  
**EMILY BERNHARDT**  
**PRIMARY EXAMINER**  
**GROUP 1600**